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Sleep quality in stroke patients receiving botulinum toxin treatment for spasticity

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Abstract
Aim: Botulinum toxin (BoNT) is widely used in the treatment of stroke-related spasticity. Sleep disturbances are often observed as a comorbidity or complication in stroke patients. In light of the data linking spasticity with sleep disorders, this study aimed to evaluate whether spasticity treatment with BoNT improved sleep quality, quality of life, and anxiety levels in stroke patients.
Materials and Methods: This observational, cross-sectional study included 38 hemiplegic patients with focal spasticity who were scheduled for BoNT injections following a stroke. Assessments were undertaken before BoNT injections and at the first and third months after treatment. Clinical evaluations included the Modified Ashworth Scale (MAS) for spasticity, the Visual Analog Scale (VAS) for pain and spasticity severity, Brunnstrom staging for hand, upper, and lower extremities, the Pittsburgh Sleep Quality Index (PSQI) for sleep quality, the Hospital Anxiety and Depression Scale (HADS-A and HADS-D) for anxiety and depression levels, and the EuroQol-5 Dimensions-5 Levels (EQ-5D-5L) for quality of life.
Results: Post-treatment assessments revealed a statistically significant reduction in Brunnstrom staging (hand, upper, and lower extremities) at both the first and third months compared to pre-treatment ($p<0.001$). Similarly, MAS, VAS, HADS-A, HADS-D, PSQI, and EQ-5D-5L scores showed significant improvements at the first and third months after treatment ($p<0.001$).
Discussion: The results of this study demonstrated that BoNT, frequently used in the treatment of stroke-related spasticity, had a positive effect on sleep quality in stroke patients.

Keywords
botulinum toxin, pittsburgh sleep quality index, sleep quality, stroke

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Introduction

Stroke is one of the leading causes of death and disability across the world. As survival rates improve, the importance of addressing post-stroke disability has become more evident [1]. One of the major contributors to post-stroke disability is spasticity, which can lead to functional impairment, pain, and deterioration in sleep and quality of life. Spasticity is defined as a sensory-motor disorder resulting from upper motor neuron lesions, characterized by intermittent or sustained involuntary muscle activation [2]. The prevalence of post-stroke spasticity has been reported to vary between 4% and 42.6% in various studies [1].

Although spasticity may contribute to standing and walking or help prevent osteoporosis and deep vein thrombosis, it is known to impair transfers, ambulation, sleep quality, and daily living activities. Treatment options for spasticity include various physical therapy modalities, pharmacological interventions, local injections (including Botulinum toxin (BoNT), and surgical treatments [3].

BoNT is a neurotoxin derived from the bacterium Clostridium botulinum, which binds presynaptically to the acetylcholine receptor at the neuromuscular junction and inhibits the release of acetylcholine, thereby blocking transmission [4]. It is effective in reducing spasticity that causes temporary, focal muscle weakness lasting three to six months [4].

BoNT is widely used in the treatment of spasticity due to its efficacy, ease of application, low side effect profile, and reversible effects. It is recommended as the first-line treatment for focal spasticity following a stroke [5]. It has been shown that the suppression of spasticity through BoNT injections leads to a reduction in functional limitations [6]. Several studies have demonstrated that the presence of spasticity after a stroke can affect sleep [2, 6]. While it is well known that BoNT treatment reduces spasticity in patients with post-stroke spasticity, there are only a few publications investigating its effects on sleep quality in these patients [7]. The primary aim of this study was to evaluate how sleep quality was affected in patients receiving botulinum toxin injection for spasticity after stroke. The secondary objective of this study is to investigate the association between sleep quality following BoNT injection and relevant demographic and clinical variables.

Materials and Methods

This study was designed as a single-center, observational, cross-sectional study. For this study, patients who received BoNT injection therapy due to post-stroke spasticity between August 2021 och March 2022 at our clinic were evaluated. A minimum grade 1 spasticity in the target muscle, where BoNT was applied, was defined as an inclusion criterion. Patients who did not meet the exclusion criteria listed below and who received the same total dose of BoNT injection (300 IU) were included in the study.

Exclusion criteria

- History of BoNT treatment,
- Any neurological disorders other than stroke,
- Uncontrolled diabetes, uncontrolled hypertension, and uncontrolled cardiovascular disease,
- Pre-existing sleep disorders
- Malignancy
- Pregnancy
- Presence of allergy or sensitivity to BoNT
- Fixed contractures i targeted muscle

In our clinic, BoNT injections were diluted with 2 mL of 0.9% NaCl and administered at a total maximum dose of 300 IU. The injections were performed by the same doctor, under ultrasound guidance, targeting the planned muscles in the upper and lower extremities.

All patients' demographic characteristics (age, gender, disease duration and etiology, and educational level) were assessed. Clinical evaluations were performed by the same researcher on the day of injection and at the first and third months after injection. Patients' upper extremities, hands, and lower extremities were evaluated functionally with Brunnstrom staging. The Brunnstrom staging system was used to evaluate the neurophysiological development stages of the patients [8]. According to this staging, patients are assessed across six stages based on the development of spasticity and synergy patterns. The lowest stage is Stage I (where voluntary movement is absent), and the highest stage is Stage VI (where isolated joint movement occurs). A higher stage indicates a better level of motor recovery in the patient. The upper extremity, lower extremity, and hands were evaluated separately.

The grade of spasticity in the muscles treated with BoNT was evaluated using the Modified Ashworth Scale (MAS) by the same physician. The spasticity grade was defined for the elbow (MAS-E), wrist (MAS-W), hand fingers (MAS-F), and ankle (MAS-A) flexor muscles. The MAS is one of the most commonly used clinical scales for assessing spasticity. The MAS was modified by Bohannan et al. in 1987 by adding +1 to the classic Ashworth scale, and its reliability has been established by practitioners [9]. This assessment consists of a scoring system with six levels (0 = no increase in muscle tone and 4 = affected part is rigid in flexion or extension). A weakness of the scale is that it is subjective and nominal. It is frequently used due to its ease of application, good tolerability by patients, lack of equipment requirement, and low cost.

Spasticity severity was also assessed by the patient using a Visual Analog Scale (VAS) for the elbow (VAS-E), wrist (VAS-W), fingers (VAS-F), and ankle (VAS-A). Both MAS and VAS spasticity assessments were conducted on the muscles targeted by the BoNT injections.

The presence and location of pain (upper/lower extremity, plegic/non-plegic side) were recorded, and the severity of pain was evaluated by using VAS. The VAS is the most widely used and easy-to-use scale for assessing pain. The patients were asked to rate their pain on a horizontal 10-cm line, scoring from 0 (no pain) to 10 (worst pain imaginable) [10].

Sleep quality was assessed using the Pittsburgh Sleep Quality Index (PSQI). The PSQI is a standardized sleep quality assessment scale developed by Buysse et al. in 1989. Validity and reliability studies have been conducted [11]. The PSQI consists of 19 items under seven subscales (subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction) rated on a scale of 0 to 3. The sum of all subscales is assessed with a total sleep quality score ranging from 0 to

21, with higher scores indicating lower sleep quality. A total score of five or higher is considered indicative of poor sleep quality [11].

Quality of life was measured using the EuroQol-5 Dimensions-5 Levels (EQ-5D-5L). The EQ-5D-5L consists of five items, each covering a specific topic. The EQ-5D-5L is a brief, multi-attribute, generic health status measure that includes Likert response options (descriptive system) and a visual analog scale (EQ-VAS) consisting of five questions. The descriptive system covers five dimensions of health (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), with five severity levels in each dimension (no problems, slight problems, moderate problems, severe problems, and extreme problems or inability). The second part (EQ-VAS) of the scale asks patients to rate their health on a scale from 0 (worst imaginable health) to 100 (best imaginable health). In this study, the Turkish version of the scale, which has been translated into 171 languages by the EuroQol group, was used [12].

The anxiety and depression levels were evaluated with the Hospital Anxiety and Depression Scale (HADS). The HADS was developed by Zigmond and Snaith, and the validity and reliability of the Turkish version were examined by Aydemir et al. [13]. The scale consists of 14 items and comprises two factors. Seven odd-numbered items measure anxiety, while seven even-numbered items measure depression. Scoring varies for each item: items 1, 3, 5, 6, 8, 10, 11, and 13 are scored as 3, 2, 1, and 0, respectively, while items 2, 4, 7, 9, 12, and 14 are scored as 0, 1, 2, and 3, respectively. In the evaluation of the scale, the cut-off score is 10 for the anxiety subscale and 7 for the depression subscale. Respondents with scores above these thresholds are considered at risk.

This study was conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained from the patients, and detailed information about the study was included in the consent form.

Statistical Analysis

Continuous variables were expressed as mean ± standard deviation values, while categorical data were expressed as frequencies and percentages. The normality of continuous variables was assessed using the Kolmogorov-Smirnov goodness-of-fit test. Comparisons between two groups were undertaken using Student's t-test if the data followed a normal distribution and the Mann-Whitney U test otherwise. Pre- and post-treatment comparisons were conducted using the Friedman Test (post hoc: Wilcoxon signed-rank test). For comparing categorical data, the chi-square test and/or Fisher's exact test were employed. The linear relationship between scales was tested using Spearman's rho correlation analysis. Analyses were performed using IBM SPSS version 26.0 (IBM Corporation, Armonk, NY, USA). The statistical significance level was accepted as $p < 0.05$.

Ethical Approval

This study was approved by the Ethics Committee of the Adana City Training and Research Hospital Clinical Research Ethics Committee (Date: 2021-07-14, No:85-KAEK-1490).

Results

The study included a total of 38 patients, of whom 60.5% were male and 39.5% were female. The mean age of the patients was 54.84 ± 13.69 years. The demographic characteristics of the patients are presented in Table 1.

It was determined that Brunnstrom staging scores (hand, upper extremity, and lower extremity) showed statistically significant improvement at the first- and third-month follow-ups compared to pre-treatment values. In addition, MAS (E, W, F, and A), VAS-spasticity (E, W, F, and A), HADS-A, HADS-D, PSQI, and EQ-5D-5L scores were found to have statistically significant reductions at both the first- and third-month follow-ups compared to pre-treatment ($p < 0.001$). In contrast, EQ-VAS scores showed a statistically significant increase at the first and third months compared to pre-treatment ($p<0.001$). However, no statistically significant differences were found between the first and third post-treatment measurements for Brunnstrom scores (hand, upper extremity, and lower extremity), MAS (E, W, F, and A), HADS-A, HADS-D, or PSQI scores ($p > 0.05$). Nevertheless, VAS-spasticity (E, W, F, and A) scores were found to be significantly higher at the third month compared to the first month after treatment (Table 2, Figures 1, 2).

Table 3 presents the first-month evaluation of patients with good and poor sleep quality after BoNT treatment according to their demographic and clinical characteristics.

No significant correlations were found between PSQI scores and other scale scores at the first-month follow-up after BoNT

Table 1. Sociodemographic and clinical data of the patients

	Patients (n = 38)
Age (year) (Mean ± SD)	54.84 ± 13.69
BMI (kg/m^2) (Mean ± SD)	27.74 ± 3.82
Disease duration (month) (Mean ± SD)	16.94 ± 11.01
Gender (n, %)	
Female	15 (39.5%)
Male	23 (60.5%)
Educational level (n, %)	
Primary school	11 (28.9%)
Middle school	12 (31.6%)
High school	13 (34.2%)
University	2 (5.3%)
Hemiplegic side (n, %)	
Right	21 (55.3%)
Left	17 (44.7%)
Etiology of stroke (n, %)	
Thromboembolic	30 (78.9%)
Hemorrhagic	8 (21.1%)
Comorbidity (n, %)	
None	12 (31.6%)
Hypertension	14 (36.8%)
Diabetes mellitus + hypertension	12 (31.6%)
Pain (n, %)	
Absent	15 (39.5%)
Present	23 (60.5%)
Painful area (n, %)	
None	15 (39.5%)
Plegic upper extremity	7 (18.4%)
Plegic lower extremity	11 (28.9%)
Plegic upper and lower extremities	5 (13.2%)

SD: standard deviation

Table 2. Comparison of pre- and post-treatment evaluations (n = 38)

	Pre-treatment Median (min–max)	Post-treatment first month Median (min–max)	Post-treatment third month Median (min–max)	p1
Brunnstrom staging-hand	2 (1–4)	3 (1–5)	3 (1–5)	<0.001*
Brunnstrom staging-upper extremity Mean ± SD)	3 (1–4) (2.64 ± 0.66)	3 (1–5) (3.41 ± 0.84)	3 (1–5) (3.38 ± 0.88)	<0.001*
Brunnstrom staging-lower extremity	3 (3–4)	4 (3–4)	4 (3–4)	<0.001*
MAS-E	3 (1.5–3)	1.5 (1–2)	1.5 (1–3)	<0.001*
MAS-W	3 (1.5–3)	1.5 (1–3)	1.5 (1–3)	<0.001*
MAS-F	3 (1.5–3)	1.5 (1–3)	1.5 (1–3)	<0.001*
MAS-A	3 (2–3)	1.5 (1–3)	1.5 (1–3)	<0.001*
VAS-E	8 (6–10)	4 (2–9)	5 (2–9)	<0.001*
VAS-W	9 (8–9)	4 (2–9)	5 (2–9)	<0.001*
VAS-F	9 (7–10)	4 (3–9)	5 (2–9)	<0.001*
VAS-A	9 (5–10)	3.5 (2–9)	4 (2–10)	<0.001*
VAS-pain	6.5 (2–8)	2 (0–8)	2.5 (0–8)	<0.001*
HADS-anxiety	7.5 (0–17)	4.5 (0–13)	5 (0–14)	<0.001*
HADS-depression	7 (0–18)	5 (0–12)	5.5 (0–13)	<0.001*
PSQI	6 (1–18)	4 (1–12)	4 (1–15)	<0.001*
EQ-5D-5L	14.5 (8–21)	10 (6–14)	11 (7–15)	<0.001*
EQ-VAS	35 (10–60)	70 (20–85)	67.5 (30–85)	<0.001*

*Friedman test (Post hoc: Wilcoxon signed-rank test). SD: standard deviation, MAS: Modified Ashworth Scale, E: elbow, W: wrist, F: finger, A: ankle, VAS: Visual Analog Scale, HADS: Hospital Anxiety and Depression Scale, PSQI: Pittsburgh Sleep Quality Index, EQ-5D-5L: EuroQol-5 Dimensions-5 Levels

Table 3. Comparison of first-month PSQI scores after BoNT treatment according to certain sociodemographic and clinical parameters

	Post-BoNT PSQI < 5 (good sleep quality) (n = 26)	Post-BoNT PSQI ≥ 5 (poor sleep quality) (n = 12)	p
Age (year) (Mean ± SD)	53.69 ± 13.69	57.33 ± 13.95	0.454*
BMI (kg/m^2) (Mean ± SD)	28.17 ± 4.04	26.80 ± 3.24	0.309*
Disease duration (month) (Mean ± SD)	12 (6-48)	12 (5-28)	0.566**
Gender (n, %)			
Female	8 (53.3%)	7 (46.7%)	0.106***
Male	18 (78.3%)	5 (21.7%)	
Educational level (n, %)			
Primary school	8 (72.7%)	3 (27.3%)	0.704***
Middle school	7 (58.3%)	5 (41.7%)	
High school	10 (76.9%)	3 (23.1%)	
University	1 (50.0%)	1 (50.0%)	
Hemiplegic side (n, %)			
Right	15 (71.4%)	6 (28.6%)	0.658***
Left	11 (64.7%)	6 (35.3%)	
Etiology of stroke (n,%)			
Thromboembolic	19 (63.3%)	11 (36.7%)	0.393****
Hemorrhagic	7 (87.5%)	1 (12.5%)	
Comorbidity (n, %)			
None	10 (83.3%)	2 (16.7%)	0.385***
Hypertension	9 (64.3%)	5 (35.7%)	
Diabetes mellitus + hypertension	7 (58.3%)	5 (41.7%)	
Pain (n, %)			
Absent	11 (73.3%)	4 (26.7%)	0.728****
Present	15 (65.2%)	8 (34.8%)	
Painful area (n, %)			
None	11 (73.3%)	4 (26.7%)	0.442***
Plegic upper extremity	3 (42.9%)	4 (57.1%)	
Plegic lower extremity	8 (72.7%)	3 (27.3%)	
Plegic upper and lower extremities	4 (80.0%)	1 (20.0%)	

*Student's t-test, **Mann-Whitney U test, ***Chi-square test, ****Fisher's exact test. PSQI: Pittsburgh Sleep Quality Index, BoNT: botulinum toxin, SD: standard deviation

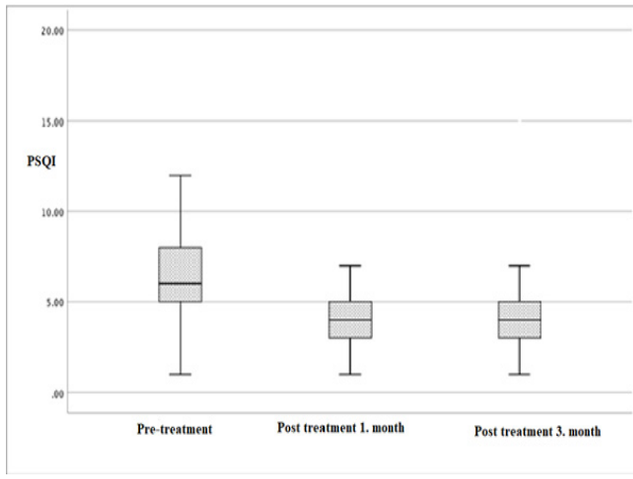

Figure 1. Graphical representation of PSQI scores before and after treatment

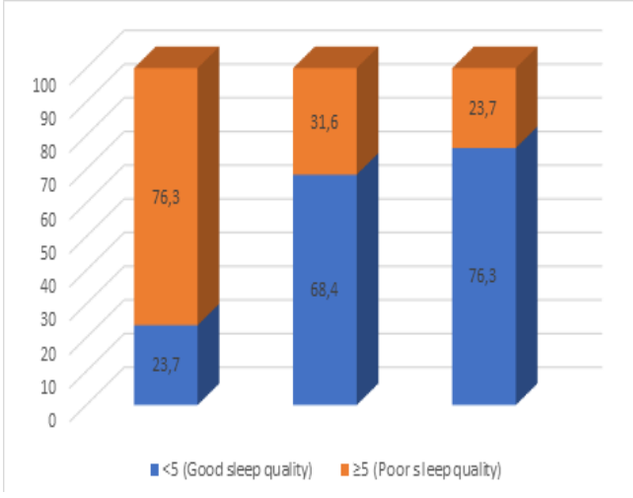

Figure 2. Distribution of good and poor sleep quality percentages before and after botulinum toxin (BoNT) treatment

treatment ($p > 0.05$). However, at the third month following treatment, a positive, moderate, and statistically significant correlation was identified between PSQI and HADS-D scores.

Discussion

This study provides insight into the changes in spasticity and sleep quality at multiple time points following BoNT injections in stroke patients. According to our findings, BoNT injections for the treatment of spasticity in stroke patients have the potential to improve sleep quality. In addition, a reduction in extremity pain, improvements in anxiety-depression scores, and enhanced quality of life were observed. The improvements in sleep quality may be related to the reduction in spasticity and pain, as well as improvements in depressive symptoms.

Several studies have explored the coexistence of stroke and sleep disorders, but there are only limited studies on sleep quality in stroke patients without a diagnosed sleep disorder [14]. In the current study, we evaluated sleep quality in stroke patients without a sleep disorder diagnosis before and after BoNT injections.

Previous research has shown that spasticity following a stroke can affect sleep [2, 6]. While it is well known that BoNT treatment reduces spasticity in stroke patients, only a few studies have examined the effect of this treatment on sleep quality. One of these studies showed similar results to ours, indicating that BoNT frequently used for treating spasticity, also has a positive impact on sleep quality [7]. Furthermore, a study on children with cerebral palsy (CP) investigated the effect of BoNT on sleep problems, concluding that BoNT injections aimed at reducing spasticity might have the potential to improve sleep quality in patients with CP [15]. In our study, we also observed a statistically significant reduction in PSQI scores following BoNT treatment, indicating an improvement in sleep quality.

In the present study, MAS at both the first and third months post-injection showed a statistically significant reduction compared to baseline. However, there is no statistically significant difference between the first and third month MAS. While the physician-rated MAS scores remained stable, the patient-reported VAS-Spasticity scores revealed a significant increase at the third month compared to the first. This divergence may point to a gradual decline in the perceived therapeutic effect of BoNT over time.

Spasticity can be a direct or indirect cause of pain [16]. Some studies involving BoNT treatment have also included pain as an outcome measure. In most studies evaluating pain, a reduction in pain was observed parallel to the reduction in spasticity [17]; there is also research reporting no change in pain despite reduced spasticity [18]. In the current study, both spasticity and pain significantly decreased following BoNT treatment. However, we found no correlation between spasticity, pain, and PSQI scores after treatment.

BoNT also possesses analgesic effects resulting from its reduction of muscle hyperactivity and therefore has been widely investigated in various pain-related conditions, including myofascial pain syndrome, headache, arthritis, and neuropathic pain [19]. Findings from these studies suggest that BoNT injections may alleviate pain [20], although this remains a subject of ongoing debate [16]. In this study, we hypothesized that BoNT could contribute to improved sleep quality, not only through its antispastic effects but also through its potential analgesic effects.

Previous research has shown an association between poor sleep quality and depression in stroke patients [21], while there are also researchers observing a higher incidence of anxiety among stroke patients with poor sleep quality [22]. In our study, the correlation between depressive symptoms and sleep quality, which was not significant in the first month, became statistically significant in the third month. This significant correlation may raise the question related to the fact that patients' increased perception of spasticity at the 3rd month compared to the 1st month, and this may negatively affect patients' psychological well-being and sleep patterns.

The discussion surrounding the effect of BoNT on functional improvement has been ongoing for many years. Numerous meta-analyses and systematic reviews have reported that BoNT reduces spasticity [23], and this reduction has been associated with improvements in quality of life [24, 25]. In our study, BoNT significantly reduced spasticity, and we observed a statistically significant increase in Brunnstrom staging and EQ-5D-5L scores, indicating functional improvement.

Limitations

The primary limitation of our study is the small sample size. Another limitation is that sleep quality was not evaluated using an objective parameter, such as polysomnography. This study may be considered a preliminary investigation into the effects of BoNT on sleep quality in stroke patients with spasticity, as there is limited research in the literature on this topic in adult patients. We consider that our study will contribute to the literature in this regard.

Conclusion

In conclusion, BoNT, which has been successfully used in spasticity treatment for many years, has a broad range of applications in various conditions involving excessive muscle activity. In addition, a substantial body of research has explored its use in pain-related conditions. Our study revealed the positive effects of BoNT on sleep quality; however, larger prospective randomized controlled trials are necessary to elucidate the underlying mechanisms of this effect.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and Human Rights Statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or compareable ethical standards.

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Conflict of Interest

The authors declare that there is no conflict of interest.

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